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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,566	02/12/2001	Bert Vogelstein	01107.00092	1623

22907 7590 01/25/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
	1642

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

09/780,566

VOGELSTEIN ET AL.

## Office Action Summary

Examiner

Art Unit

Natalie A. Davis

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) Responsive to communication(s) filed on 28 November 2001.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-34 are subject to restriction and/or election requirement.

## Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7 and 11-13, drawn to a reporter construct and host cell, classified in class 536, subclass 23.1.
  - II. Claims 8-10, drawn to a method of screening compounds for anti-cancer activity comprising contacting a c-MYC protein with a reporter, classified in class 435, subclass 7.1.
  - III. Claim 14, drawn to a method of screening compounds for anti-cancer activity comprising contacting a c-MYC protein with a nucleic acid, classified in class 435, subclass 6.
  - IV. Claims 15-24, drawn to a method of inhibiting tumor cell growth, classified in class 514, subclass 2.
  - V. Claim 25-32, drawn to a method of screening compounds for anti-cancer activity, comprising determining which test compound inhibits CDK4 activity, classified in class 435, subclass 6.
  - VI. Claims 33-34, drawn to a method of determining responsiveness to an anti-cancer agent, classified in class 435, subclass 91.2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I (product) and II -VI (methods) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I may be used for a number of different processes that are very much unrelated. For example, the nucleic acid of Group I may not only be used in the method of Groups II -VI, but may also be used in the synthesis of a protein. Furthermore, the methods of Groups II -VI may be practiced using a different reporter construct and not necessarily the nucleic acid molecules of Groups I.

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3. The methods of Groups II-VI relate to methods but each method differs in method steps, modes of operation, reagents needed and serve different endpoints and effects. For example, the method of Group II comprises determining decreased expression of a reporter protein, which differs from determining which test compound inhibits CDK4 activity (Group V) or identifying a test compound that decreases c-MYC binding to a nucleic acid (Group III).

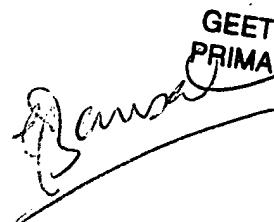
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and require different search strategies, restriction for examination purposes as indicated is proper. Applicant is advised that the response to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD  
January 22, 2002

  
GEETHA P. BANSAL  
PRIMARY EXAMINER